K002786



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**510K SUMMARY**
**Prepared Aug. 28, 2000**

1. **Submitted by:**
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2. **Contact Person:**
Jorge Haider

3. **Device Identification:**

| | |
|---|---|
| Trade Name: | Central Venous Catheter and Central Venous Catheter Kits |
| Common Name: | Central Venous Catheter / Central Venous Pressure Catheter and Kits |
| Classification Name: | Short-term Intravascular Catheter and Accessories |

4. **Predicate Device(s):**
Arrow International, Inc.'s Central Venous Catheters with Flexible Tips

5. **Device Description:**
Central Venous Catheters consist of a suitable length of flexible, radiopaque, biocompatible tubing affixed at one end to a rigid, plastic hub. The other end of the tubing is open to permit the influx or egress of fluids, or the monitoring of pressures. The hub is configured to mate with other access device components, typically by incorporating a Luer lock port. Tubing may be single or multiple lumen. Multiple lumen tubing provides multiple access channels to the central venous circulation through a single insertion site.

Central Venous Catheters are typically packaged in kits along with components that are used to facilitate their insertion into the vasculature and securement at the insertion site.

6. **Intended Use:** Biosensors CVC's are designed for use in critical care patients to monitor central venous pressures; sample venous blood; and administer drugs and solutions intravenously. Multiple lumen catheters provide multiple access channels to the central venous circulation through a single insertion site, permitting several functions to be performed simultaneously.

7. **Summary of Technological Characteristics of Device in relation to Predicate Device(s):** The primary difference between BSI's CVCs and predicate devices is in the polyurethane formulations used to fabricate catheter tubing.

K002786



8. **Assessment of Performance Data used to justify Substantial Equivalence Claim:** BSI's CVCs were evaluated in accordance with ISO 10555-1 and –3 which are recognized as consensus standards by the FDA. The catheters were found to meet or exceed the requirements of the ISO standards, or perform as well as better than predicate devices. The following characteristics were evaluated: Tensile strength and elongation at break; catheter stiffness; burst pressure; catheter leak. In addition, all materials were shown to meet biocompatibility requirements outlined in ISO 10993.

9. **Conclusion:**
Based on the test data gathered, Biosensors CVCs are substantially equivalent to Arrow Central Venous Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 7 2000

Mr. Jorge Haider
Regulatory Affairs
Biosensors International-USA, Incorporated
20250 Acacia Street, Suite 115
New Port Beach, California 92660

Re: K002786
Trade Name: Biosensors Central Venous Catheter Kits
Regulatory Class: II
Product Code: FOZ
Dated: August 28, 2000
Received: September 7, 2000

Dear Mr. Haider:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set

forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

**510 (k) Number (if known)** K002786

**Device Name** Biosensors International Central Venous Catheter Kits

**Indications for Use**

Biosensors Central Venous Catheters are designed for use in critical care patients to monitor central venous pressures; sample venous blood; and administer drugs and solutions intravenously. Multiple lumen catheters provide multiple access channels to the central venous circulation through a single insertion site, permitting several functions to be performed simultaneously.

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002786

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